

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

FMC CORPORATION,

Plaintiff,
v.

SHARDA USA LLC,

Defendant.

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CIVIL ACTION

NO. 24-2419

PEREZ, J.

July 10, 2024

MEMORANDUM

This is a patent infringement action brought by FMC Corporation (“FMC”) against Sharda USA LLC (“Sharda”). The matter before the Court is FMC’s motion for a temporary restraining order and preliminary injunction to prohibit Sharda from importing, marketing, advertising, selling, or distributing its WINNER insecticide or any insecticide comprising a combination of bifenthrin and a cyano-pyrethroid in a ratio between about 10:1 to about 1:100. FMC alleges that the WINNER insecticide literally infringes at least claims 1-3 and 6 of U.S. Patent No. 9,596,857 (“the ‘857 Patent”) and claims 1-2, 4-14 and 16 of U.S. Patent No. 9,107,416 (“the ‘416 Patent”). Importantly, FMC’s HERO® insecticide practices the ‘857 and ‘416 Patents (collectively, “the asserted patents”).

The Court held an evidentiary hearing on the motion, wherein the parties presented argument, evidence, and witness testimony. After careful assessment of the parties’ briefing, the arguments advanced at the hearing, and the overall record, the Court concludes that FMC has not established a likelihood of success in proving infringement. Therefore, neither a temporary restraining order nor preliminary injunction are warranted at this time.

I. BACKGROUND

A. The Asserted Patents and the Accused Product

The '857 and '416 Patents are assigned to FMC and cover its HERO® insecticide. ECF 1 at ¶¶ 10, 16. HERO® is a highly effective premixed sprayable insecticide that combines bifenthrin and zeta-cypermethrin in a 3:1 ratio of bifenthrin (11.25% weight by volume) to zeta-cypermethrin (3.75% weight by volume). *Id.* at ¶ 17. HERO®'s superior treatment of insects and protection of crops, among other qualities, have led to it becoming a dominant product in the market. *Id.* at ¶ 16.

A primary dispute in this action is how the asserted patents' claims should be construed. Claim 1 of the '857 Patent is the only independent claim and can be broken down into the following elements:

1. An insecticidal composition comprising
2. bifenthrin and
3. a cyano-pyrethroid selected from the group consisting of acrinathrin, cycloprothrin, deltamethrin, tralomethrin, fenvalerate, cyfluthrin, beta-cyfluthrin, flucythrinate, alpha-cypermethrin, beta-cypermethrin, theta-cypermethrin, zeta-cypermethrin, cyphenothrin, cyhalothrin, lambda-cyhalothrin, esfenvalerate, fluvalinate and fenpropathrin
4. wherein the composition has a ratio of bifenthrin:cyano-pyrethroid of from about 10:1 to about 1:100.

ECF 1-1 at 13. The only independent claims of the '416 Patent are claims 1, 5, and 11. Claim 1 consists of the following elements:

1. A miticidal composition comprising
2. bifenthrin and
3. a cyano-pyrethroid selected from the group consisting of deltamethrin, cyfluthrin, alpha-cypermethrin, zeta-cypermethrin, lambda-cyhalothrin, and esfenvalerate
4. wherein the weight ratio of bifenthrin to cyano-pyrethroid is from 10:1 to 1:30.

Id. at 22. The breakdown for claim 5 is:

1. A method for controlling unwanted insects or mites comprising applying a composition comprising
2. bifenthrin and


3. a cyano-pyrethroid selected from the group consisting of deltamethrin, cyfluthrin, alpha-cypermethrin, zeta-cypermethrin, lambda-cyhalothrin, and esfenvalerate
4. wherein the weight ratio of bifenthrin to cyano-pyrethroid is from 10:1 to 1:30
5. to the foliar portion of a plant.

Id. Lastly, the elements of claim 11 are:

1. A foliar insecticidal or miticidal composition comprising
2. bifenthrin and
3. a cyano-pyrethroid selected from the group consisting of deltamethrin, cyfluthrin, alpha-cypermethrin, zeta-cypermethrin, lambda-cyhalothrin, and esfenvalerate
4. wherein the weight ratio of bifenthrin to cyano-pyrethroid is from 10:1 to 1:30.

Id. at 23.

FMC brought this action upon learning that Sharda imported into the United States a premixed insecticide that also contains a formula of 11.25% bifenthrin and 3.75% zeta-cypermethrin, which correlates to a 3:1 ratio of bifenthrin to zeta-cypermethrin. ECF 1 at ¶ 22. Sharda has labeled this product “WINNER.” *Id.* A comparison of the HERO® and WINNER product labels illustrate their identical formulation of active ingredients:



The label for HERO Insecticide features a yellow circle with a white star above the word "HERO" in large, bold, black letters. Below "HERO" is a thick purple horizontal bar. Underneath the bar, the word "INSECTICIDE" is written in a smaller, spaced-out font. To the left of "INSECTICIDE" is "EPA Reg. No. 279-3315" and to the right is "EPA Est. 279-NY-1". Below this is a table of active ingredients.

Active Ingredients:	By Wt.
Zeta-Cypermethrin*	3.75%
Bifenthrin**	11.25%
Other Ingredients***:	85.00%
	100.0%

HERO Insecticide contains 0.309 pound zeta-cypermethrin and 0.927 pound bifenthrin per gallon.
 * Cis/trans isomer ratio: Max 75% (±) cis and Min. 25% (±) trans
 ** Cis isomers 97% minimum; trans isomers 3% maximum.
 *** Contains Petroleum Distillates.

ZETA-CYPERMETHRIN		GROUP	SA	INSECTICIDE
Winner				
ACTIVE INGREDIENTS:				WT. BY %
Bifenthrin: (2-methyl [1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyclopropanecarboxylate.				11.25%
Zeta-Cypermethrin: (S)-cyano(3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate,				3.75%
OTHER INGREDIENTS*:				85.00%
TOTAL:				100.00%
Contains 0.927 pound bifenthrin and 0.309 pound zeta-cypermethrin per gallon.				
*Cis isomers 97% minimum; trans isomers 3% maximum.				
**Cis/trans isomer ratio: Max 75% (±) cis and Min, 25% (±) trans				
*Contains Petroleum Distillates.				

Because WINNER is an insecticide that contains bifenthrin and a cyano-pyrethroid, zeta-cypermethrin, at a ratio of 3:1, FMC contends that Sharda infringes on at least claims 1-3 and 6 of the '857 Patent and claims 1-2, 4-14 and 16 of the '416 Patent.

B. The Parties' Arguments

In its Motion, FMC argues that a plain reading of the asserted patents' claims compared with the WINNER insecticide's product label shows that WINNER literally infringes on the asserted patents. ECF 4 at 8; *see also* ECF 1-1. FMC further argues that the asserted patents enjoy a presumption of validity unless Sharda challenges their validity. *Id.* In response, Sharda mounts a validity challenge, contending that the asserted patents are invalid because a 1996 article written by an FMC employee (hereinafter, "the McKenzie article") anticipates the asserted patents. ECF 11 at 5.

The McKenzie article studied pyrethroid insecticides as applied to immature and adult whitefly. *See* ECF 11-3. Two of the pyrethroid treatments were well-known FMC compositions: Mustang 1.5 EW and Capture 2EC. *Id.* Mustang 1.5 EW is an insecticide with zeta-cypermethrin,

a cyano-pyrethroid, as its active ingredient. ECF 11-5 at 5. Capture 2EC is an insecticide/miticide with bifenthrin as its active ingredient. ECF 11-4 at 2. Mustang 1.5 EW and Capture 2EC were used in a tank mixture¹ at a ratio of 1:1.45 and applied to small plot fields with cotton plants. ECF 11-1 at ¶ 49; ECF 11-3. Because the McKenzie article discloses an insecticidal composition that includes bifenthrin (Capture 2EC) and zeta-cypermethrin (Mustang 1.5 EW) at a ratio from about 10:1 to about 1:100, Sharda argues the McKenzie article anticipates the asserted patents' claims. As a result, Sharda has established a substantial question of validity, so the argument goes.

FMC replies that Sharda's anticipation argument lacks substantial merit because unlike the tank mixture studied in the McKenzie article, the intrinsic record shows that the asserted patents are surprisingly effective and stable. Because the McKenzie article does not disclose every limitation of the asserted patents' claims—specifically, a *stable and effective* composition containing bifenthrin and a cyano-pyrethroid—the McKenzie article does not anticipate the asserted patents. It is also FMC's position that, although Capture 2EC is approved as a miticide, the McKenzie article is silent on miticidal use and therefore does not anticipate the '416 Patent's claims.

II. DISCUSSION

To succeed in seeking a preliminary injunction, a plaintiff must establish: (1) a likelihood of success on the merits; (2) it will suffer irreparable harm without a preliminary injunction; (3) the balance of equities weighs in favor of issuing a preliminary injunction; and (4) an injunction is in the public interest. *Winter v. National Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The Third Circuit has described the first two requirements as “gateway factors.” *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017). If the gateway factors are met, then a court should

¹ “Tankmix partners are agricultural products that can be mixed in a spray tank according to the product label.” ECF 17-1.

consider the remaining factors. *Id.*; see also *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) (“[A] movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm”).

Demonstrating a likelihood of success in a patent infringement case requires a plaintiff to “show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent.” *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). “If [the defendant] raises a substantial question concerning either infringement or validity, *i.e.*, asserts an infringement or invalidity defense that the patentee cannot prove ‘lacks substantial merit,’ the preliminary injunction should not issue.” *Amazon.com, Inc.*, 239 F.3d at 1350-51. The Court must assess infringement and validity on a claim-by-claim basis. *Id.* at 1351.

Courts apply a two-step process when assessing infringement. *Id.* First, a claim is construed to determine its scope and meaning. *Id.* Second, “the properly construed claim is compared with the accused device to determine whether all of the claim limitations are present either literally or by a substantial equivalent.” *Id.* Once a claim is properly construed, then a court can assess a patent’s validity. *Id.* An invention is invalid if it was “described in a printed publication . . . more than one year prior to the date of application for patent in the United States.” 35 U.S.C. § 102(b) (pre-AIA). “A claim is anticipated if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference.” See *Arbutus Biopharma Corp. v. ModernaTX, Inc.*, 65 F.4th 656, 662 (Fed. Cir. 2023).

A. Claim Construction

“Claim terms are generally given their plain and ordinary meanings to one of skill in the art when read in the context of the specification and prosecution history.” *Hill-Rom Servs., Inc. v.*

Stryker Corp., 755 F.3d 1367, 1371 (Fed. Cir. 2014). The prosecution history is part of the intrinsic record and “contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term.” *Id.* at 1583.

The parties dispute the meaning of the claim term “composition.” See ECF 1-1 at 13 (the ‘857 Patent claiming “[a]n insecticidal composition”) and ECF 1-1 at 22 (the ‘416 Patent claiming “[a] miticidal composition” and “[a] foliar insecticidal or miticidal composition”). FMC argues that the intrinsic record indicates the claims cover only stable compositions. Sharda counters that adding a stability requirement would improperly narrow the claims rather than give them their plain and ordinary meanings.

In support of its argument, FMC points to the following evidence: the asserted patents’ specifications, the provisional application, U.S. Patent No. 8,153,145 (“the ‘145 Patent”), and the notices of allowance for the asserted patents. To start, the ‘145 Patent was filed by FMC with the same effective filing date as the asserted patents, claims the same priority to the provisional application, and was cited by the patent examiner during the prosecution of the asserted patents. See ECF 17-1 at ¶ 23, ECF 17-7 (‘416 Patent) & ECF 17-9 (‘857 Patent). The ‘145 Patent recognized the instability and ineffectiveness of tank mixtures like the one described in the McKenzie article and distinguished those type of combinations from the patented invention. Using a tank mixture of commercially available bifenthrin (Capture 2EC) and zeta-cypermethrin (Mustang Max 0.8EC) as a control, the ‘145 Patent explained that “[t]he novel formulations of the present invention are superior in maintaining the physical stability of a mixture of bifenthrin and

zeta-cypermethrin in dilution stability tests when compared to the control dilution stability test.” *See* ‘145 Patent. Indeed, “[t]he physical stability of the [tankmix] formulation when diluted with water is a key problem in the art.” *Id.*

The provisional application of the asserted patents also discloses this problem with tank mixtures and its impact on efficacy. *See* ECF 17-6 (“[A] problem in the art of formulating bifenthrin and zeta-cypermethrin is in successfully achieving physical stability of a water-diluted mixture of the formulation over significant periods of time. Physical stability is most important in this type of formulation to ensure the small amounts of the insecticides are fully effective”). In essence, simple combinations of bifenthrin insecticide products and zeta-cypermethrin insecticide products have been proven unstable which has led to ineffective performance. By contrast, the specifications of the asserted patents describe the “unexpected insecticidal activity” achieved by the patented compositions. *See* ECF 1-1 at 7, 1:48-50 (‘857 Patent); ECF 1-1 at 16, 1:14 (‘416 Patent). These unexpected superior results contributed to the allowance of the asserted patents. *See* ECF 17-8 (explaining the ‘416 Patent’s formulation “provide[s] unexpectedly desirable control of several insect and mite species when employed in the claimed ratios); ECF 17-10 (same with regard to the ‘857 Patent).

Therefore, when viewed in the context of the intrinsic record, the claim term “composition” must be construed to mean stable compositions, rather than the well-known unstable compositions that produce ineffective results as discussed throughout the prosecution history. Having resolved this issue, the Court now turns to comparing the properly construed claims to the WINNER insecticide.

B. Application

“For literal infringement, the patentee must prove that the accused product meets all the limitations of the asserted claims; if even one limitation is not met, there is no literal infringement.” *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1073 (Fed. Cir. 2019). Similarly, to anticipate a claim, a prior art must teach each limitation of the asserted claim. *Id.* at 1074.

In its opening brief, FMC first argued that a plain and ordinary reading of the claims demonstrates infringement—there was no mention of stability as a limitation to the claims. Then, upon Sharda’s argument that the McKenzie article anticipates the claims, FMC argued that stability is a limitation to the claims that differentiates the asserted patents from the tank mixtures studied in the McKenzie article. However, “claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses.” *Amazon.com, Inc.*, 239 F.3d at 1351.

This Court has accepted FMC’s claim construction arguments and determined that stability is a limitation to the asserted claims. It appears FMC did not appreciate, however, that this limitation must apply to both the infringement and validity analyses. In arguing that Sharda’s validity challenge lacks substantial merit because the formulation studied in the McKenzie article was neither stable nor effective, FMC highlighted a key problem: the record is devoid of any evidence regarding WINNER’s stability or efficacy. FMC’s key witness, Dr. Neil Young, testified that FMC did not test WINNER’s stability or efficacy because it does not have WINNER in its possession. ECF 23 at 62:23-25. FMC was also unable to point to any other studies that bear on WINNER’s stability. FMC cannot on one hand, argue that the asserted patents are valid because HERO® is stable and effective, and then on the other hand, prove that WINNER infringes on the asserted patents without demonstrating that it is also a stable and effective composition.

Indeed, “[a] patent may not, like a ‘nose of wax,’ be twisted one way to avoid anticipation and another to find infringement.” *Amazon.com, Inc.*, 239 F.3d at 1351 (quoting *Sterner Lighting, Inc. v. Allied Elec. Supply, Inc.*, 431 F.2d 539, 544 (5th Cir. 1970)). Until FMC is able to establish WINNER’s stability or efficacy, the request for a preliminary injunction is premature. Without such evidence, this Court is unable to hold that WINNER meets all of the limitations of the asserted claims. FMC is therefore unable to establish a likelihood of success in proving infringement.

Because a movant is not entitled to a preliminary injunction in a patent infringement case if it fails to demonstrate a likelihood of success in proving infringement, this Court declines to address the validity arguments and remaining preliminary injunction factors. Accordingly, the motion for a temporary restraining order and preliminary injunction is denied without prejudice.

An appropriate order follows.